

FROM : PEDIATRIC NEUROLOGY

FAX NO. : 513 6361063

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PATENT**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

Applicant: Tang et al. : Paper No:
Serial No. 10/090,347 : Group Art Unit: 1651
Filed: March 4, 2002 : Examiner: A. Nogueroles
For: ELECTROCHEMICAL ANALYSIS OF COENZYME Q10 AND REDUCED
COENZYME Q10

DECLARATION UNDER 37 C.F.R. 1.131

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Michael V. Miles declares that:

- 1) Peter H. Tang, Ton de Grauw and I, have been determined by our patent attorney as being the inventors for the above-captioned application. I am familiar with the content of that application.
- 2) I, along with Peter H. Tang and Ton de Grauw, Andrew Hershey and Arnadeo Pesce, are co-authors of the research paper entitled "HPLC Analysis of Reduced Coenzyme Q10 in Human Plasma," *Clinical Chemistry*, vol. 47, pp. 256-65. This paper was cited by the Examiner as the basis for a rejection under 35 U.S.C. §102(a), in the June 2, 2004 office action.
- 3) This article describes the Applicants' own work and was performed in the Applicants' laboratory and thus cannot be prior art under 35 U.S.C. §102(a), since this work was not "invented by another."

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- 4) There are two additional co-authors listed on this publication that are not listed as inventors for this pending application, they are Andrew Hershey and Amadeo Pesce.
- 5) Andrew Hershey is a professor at Children's Hospital in Cincinnati, Ohio and Amadeo Pesce is a professor at the University of Cincinnati College of Medicine, Cincinnati, Ohio. Professors Hershey and Pesce merely participated in discussion groups during the early phase of this research.
- 6) The article cited by the Examiner in *Clinical Chemistry* is a research paper and in research papers, those individuals who have been involved in discussion groups related to the research may be listed as co-authors but are not considered to be co-inventors, as the standard for authorship is different from the legal standard for inventorship.
- 7) All information contained in this Declaration is true, or if based on information and belief, is believed to be true. I understand that, under 18 U.S.C. 1001, willful false statements and the like may be punished by fine or imprisonment, or both, and can result in the invalidity of any patent which is based on those statements.



Michael V. Miles, Pharm. D.